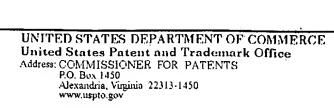


## United States Patent and Trademark Office



| APPLICATION NO.   | FILING DATE              | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|--------------------------|----------------------|-------------------------|------------------|
| 10/014,950  | 12/11/2001               | John K. Thottathil   | LD74A DIV I             | 3992             |
| 23914 7:  | 590 09/24/2003           |                      |                         |                  |
| STEPHEN B. DAVIS BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT |                          |                      | EXAMINER .              |                  |
|   |                          |                      | TRINH, BA K             |                  |
| P O BOX 4000  |                          |                      |                         |                  |
| PRINCETON,  | PRINCETON, NJ 08543-4000 |                      | ART UNIT                | PAPER NUMBER     |
|   |                          |                      | 1625                    |                  |
|   |                          |                      | DATE MAILED: 09/24/2003 | (                |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |  | Application No.  | Applicant(s)  |  |  |  |
|--|--|--|---|--|--|--|
|  | •  | 10/014,950   | THOTTATHIL ET AL.   |  |  |  |
|  | Office Action Summary  | Examin r   | Art Unit  |  |  |  |
|  |  | Ba K. Trinh  | 1625  |  |  |  |
| Davis d 6  | The MAILING DATE of this communication ap  | pears n the c ver sheet with the   | correspondence address  |  |  |  |
| THE  | ORTENED STATUTORY PERIOD FOR REPLEMAILING DATE OF THIS COMMUNICATION.  In the control of the con |  |   |  |  |  |
| after<br>- If the<br>- If NC<br>- Failu<br>- Any | SIX (6) MONTHS from the mailing date of this communication. e period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period are to reply within the set or extended period for reply will, by statutore reply received by the Office later than three months after the mailing patent term adjustment. See 37 CFR 1.704(b).  | oly within the statutory minimum of thirty (30) da<br>will apply and will expire SIX (6) MONTHS from<br>e, cause the application to become ABANDON | ays will be considered timely. m the mailing date of this communication. IED (35 U.S.C. § 133). |  |  |  |
| 1)[🖂   | Responsive to communication(s) filed on 12/  | /11/2001 .   |   |  |  |  |
| 2a)□   |  | his action is non-final.   |   |  |  |  |
| 3)   | Since this application is in condition for allow   |  | prosecution as to the merits is   |  |  |  |
| •  | closed in accordance with the practice under ion of Claims   |  |   |  |  |  |
| 4)[🖂   | Claim(s) <u>1-8,13-21,26</u> is/are pending in the a   | pplication.  |   |  |  |  |
|  | 4a) Of the above claim(s) 13, 26 is/are withdrawn from consideration.  |  |   |  |  |  |
| 5)   | Claim(s) is/are allowed.   |  |   |  |  |  |
| 6)⊠  | Claim(s) 1-8,14-21 is/are rejected.  | ·  |   |  |  |  |
| 7)   | Claim(s) is/are objected to.   |  |   |  |  |  |
| 8)□  | Claim(s) are subject to restriction and/o  | or election requirement.   |   |  |  |  |
| Applicat   | ion Papers   | ·  |   |  |  |  |
| 9)   | The specification is objected to by the Examine  | er.  |   |  |  |  |
| 10)🛛   | The drawing(s) filed on <u>11 December 2001</u> is/a   | are: a)⊠ accepted or b)⊡ objected  | I to by the Examiner.   |  |  |  |
|  | Applicant may not request that any objection to the  | ·  | ` '   |  |  |  |
| 11)[_]   | The proposed drawing correction filed on   |  | oved by the Examiner.   |  |  |  |
|  | If approved, corrected drawings are required in re   |  |   |  |  |  |
|  | The oath or declaration is objected to by the Ex   | xaminer.   |   |  |  |  |
| Priority (                                       | ınder 35 U.S.C. §§ 119 and 120   |  |   |  |  |  |
| 13)  | Acknowledgment is made of a claim for foreig   | n priority under 35 U.S.C. § 119(  | a)-(d) or (f).  |  |  |  |
| a)   | ☐ All b)☐ Some * c)☐ None of:  |  |   |  |  |  |
| -  | 1. Certified copies of the priority documen  | ts have been received.   |   |  |  |  |
|  | 2. Certified copies of the priority documents have been received in Application No   |  |   |  |  |  |
| * 5  | 3. Copies of the certified copies of the price application from the International Buse the attached detailed Office action for a list  | ureau (PCT Rule 17.2(a)).  | · ·   |  |  |  |
|  | Acknowledgment is made of a claim for domest   |  |   |  |  |  |
|  | ) The translation of the foreign language pro  | •  |   |  |  |  |
|  | Acknowledgment is made of a claim for domes  |  |   |  |  |  |
| Attachmen  |  |  |   |  |  |  |
|  | ee of References Cited (PTO-892)   | 4) 🔲 Interview Summa   | ry (PTO-413) Paper No(s)  |  |  |  |
|  | e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s)  | 5) Motice of Informal  | Patent Application (PTO-152)  |  |  |  |
| J.S. Patent and T                                |  |  |   |  |  |  |
| PTOL-326 (R                                      |  | ction Summary  | Part of Paper No. 5   |  |  |  |

Application/Control Number: 10/014,950

**Art Unit: 1625** 

Claims 1-8, 13-21, 26 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, 14-21, are drawn to a process of making taxane, classified in class 549, subclass 510.
- II. Claims 13, 26, are drawn to an acid ester, classified in class 560, subclass 19.

The above delineated group are distinct because of their recognized divergent subject matter based on their different classifications and their chemical structures. A search of one group is not required for the search of other group and vice versa. A reference of one group would not suggest and/or render the other group obvious in the absence of the secondary teachings. Thus, the restriction requirement as indicated is deemed proper.

During a telephone conversation with Mr. Kenneth Peist on September 5, 2003 a provisional election was made with traverse to prosecute the invention of I, claims 1-8, 14-21. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13 and 26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Application/Control Number: 10/014,950

**Art Unit: 1625** 

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mas et al.

Mas et al teaches a process of making taxanes wherein oxazolidine reacts with baccatin  ${\rm III}$  to form the taxanes. The prior art oxazolidine (compound  ${\rm VII}$  in the abstract) contains  ${\rm R}_3$  and  ${\rm R}_4$  groups being alkyl and  ${\rm R}_5$  group being alkoxy which are analogous to the current  ${\rm R}_5$  and  ${\rm R}_6$  and  ${\rm R}_1$  respectively based on the analogy of the alkyl group. Thus, it would be prima facie obvious to modify the process of Mas et al by using the analogous oxazolidine of Mas et al to react with baccatin  ${\rm III}$  to form taxane derivatives without the unobvious and/or unexpected results.

Claims 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Commercon et al.

Commercon et al teaches a process of making taxanes wherein oxazolidine reacts with baccatin III to form the taxanes. The prior art oxazolidine (compound VII in the abstract) contains R<sub>3</sub> group being alkoxy and R<sub>1</sub> group being benzoyl or alkoxy carbonyl (R<sub>2</sub> being alkyl) which are analogous to the current OR<sup>8</sup> group and R<sub>1</sub> group respectively based on the analogy of the alkyl group and the aryl group embraces phenyl as a species (benzoyl moiety). Thus, it would be prima facie obvious to modify

Application/Control Number: 10/014,950

Art Unit: 1625

Page 4

the process of Commercon et al by using an analogous oxazolidine of Commercon et al to reacts with baccatin III to form taxane derivatives in the absence of unobvious and/or unexpected results.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ba Trinh whose telephone number is 308-4545. The examiner can normally be reached on Monday-Friday 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Trinh/tgd September 9, 2003

BAK. TRINH
PRIMARY EXAMINER
GROUP 1200 / (